

What is claimed:

1. An assembly for effecting the condition of a mitral valve annulus of a heart comprising:

5 a guide wire configured to be fed into the coronary sinus of the heart; and

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a mitral valve annulus device configured to be slidingly received on the guide wire and advanced into the coronary sinus of the heart on the guide wire and that
10 reshapes the mitral valve annulus when in the coronary sinus of the heart.

2. The assembly of claim 1 wherein the guide wire is an elongated coil.

15 3. The assembly of claim 1 wherein the mitral valve annulus device has opposed ends and includes a guide wire engaging structure at at least one of the opposed ends.

20 *gk* 4. The assembly of claim 3 wherein the guide wire engaging structure includes a bore dimensioned to permit the guide wire to pass therethrough.

25 5. The assembly of claim 4 wherein the device further includes a guide wire confining channel extending between the opposed ends.

6. The assembly of claim 4 wherein the bore of the guide wire engaging structure is cylindrical in configuration.

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7. The assembly of claim 6 wherein the device further includes a guide wire confining channel extending between the opposed ends and aligned with the bore.

5 8. The assembly of claim 1 wherein the guide wire is formed of a material visible under X ray fluoroscopy.

9. The assembly of claim 1 wherein at least a portion of the device is visible under X ray fluoroscopy.

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10. The assembly of claim 1 wherein the device is visible under X ray fluoroscopy.

11. The assembly of claim 1 further including an elongated
15 introducer configured to be slidably received on the guide wire proximal to the device.

12. The assembly of claim 11 wherein the introducer is an elongated coil.

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13. The assembly of claim 11 wherein the device includes a proximal end, the introducer includes a distal end, and wherein the assembly further includes a releasable locking mechanism configured to releasably lock the proximal end of the device to
25 the distal end of the introducer.

14. The assembly of claim 13 wherein the releasable locking mechanism includes a locking pin and a complimentary detented locking groove.

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15. The assembly of claim 11 further including a guide tube having an inner lumen dimensioned for receiving the guide wire and the device and introducer when the device and introducer are slidably received on the guide wire.

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16. A method of deploying a mitral valve annulus constricting device within the coronary sinus of a heart, the method including the steps of:

10 A. providing an elongated flexible guide wire having a cross sectional dimension;

B. feeding the guide wire into the coronary sinus of the heart;

15 C. providing an elongated flexible guide tube having an inner lumen, the inner lumen having a cross sectional dimension greater than the cross sectional dimension of the guide wire;

D. feeding the guide tube into the coronary sinus of the heart over the guide wire with the guide wire within the inner lumen of the guide tube;

20 E. providing a mitral valve annulus device configured to be slidably received on the guide wire and within the inner lumen of the guide tube, the device including a proximal end;

25 F. providing a flexible elongated introducer configured to be slidably received on the guide wire and within the inner lumen of the guide tube, the introducer having a distal end;

G. placing the device onto the guide wire;

H. placing the introducer onto the guide wire;

30 I. engaging the distal end of the introducer with the proximal end of the device;

J. pushing the device with the introducer in a distal direction along the guide wire and within the guide tube until the device is at least partially encircling the mitral valve within the coronary sinus of the heart; and

5 K. withdrawing the introducer and the guide tube from the heart.

17. The method of claim 16 wherein the engaging step includes the step I(1) of releasably locking the proximal end of
10 the device to the distal end of the introducer.

18. The method of claim 17 including the further step J(1) of releasing the proximal end of the device from the distal end of the introducer prior to withdrawing the introducer.
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19. The method of claim 18 including the further step L of testing the effectiveness of the device after the withdrawing step.

20 20. The method of claim 19 including the further steps of replacing the device with a further device, the replacing steps including:

feeding the guide tube into the coronary sinus of the heart over the guide wire and the device;

25 feeding the introducer over the guide wire and into the guide tube;

releasably locking the distal end of the introducer to the proximal end of the device in a proximal direction and from the guide tube; and

30 repeating steps E and G through L with a further device.

21. A method of determining the crossover point of the circumflex artery and coronary sinus of a heart, the method including the steps of:

5 inserting a first elongated flexible rod into the coronary sinus, the first rod being visible under X ray fluoroscopy;

 inserting a second elongated flexible rod into the circumflex artery, the second rod being visible under X ray
10 fluoroscopy; and

 subjecting the heart to X ray fluoroscopic examination to determine the crossover point of the first and second rods.

15 22. A method of deploying a mitral valve annulus therapy device within the coronary sinus of a heart, the method including the steps of:

 inserting a first wire into the circumflex artery of the heart, the first wire being visible under X ray
20 fluoroscopy;

 inserting a second wire into the coronary sinus of the heart, the second wire being visible under X ray
 fluoroscopy;

 subjecting the heart to X ray fluoroscopic examination
25 to visualize the crossover point of the first and second wires; and

 deploying an elongated mitral valve annulus therapy device within the coronary sinus in a position such that the distal end of the device is proximal to the crossover
30 point of the first and second wires.

23. The method of claim 22 wherein the deploying step includes guiding the device into the coronary sinus on the second wire.

5 24. The method of claim 23 wherein the deploying step further includes the steps of slidably mounting an elongated flexible introducer onto the second wire proximal to the device, engaging the distal end of the introducer with the proximal end of the device, and pushing the device distally into the coronary
10 sinus with the introducer.

25. The method of claim 24 including the further step of withdrawing the introducer after deploying the device.

15 26. The method of claim 25 wherein the engaging step includes releasably locking the proximal end of the device to the distal end of the introducer.

20 27. The method of claim 26 including the further step of releasing the proximal end of the device from the distal end of the introducer prior to withdrawing the introducer.

28. The method of claim 24 including the further steps of:
25 providing an elongated flexible guide tube having an inner lumen, the inner lumen having a cross sectional dimension greater than the cross sectional dimension of the second wire, and the guide tube being transparent to X ray fluoroscopy;

30 feeding the guide tube into the coronary sinus of the heart over the second wire with the second wire within the inner lumen of the guide tube; and

wherein the pushing step includes pushing the device along the second wire and within the guide tube.

29. The method of claim 28 wherein the engaging step
5 includes releasably locking the proximal end of the device to the distal end of the introducer.

30. The method of claim 29 including the further steps of releasing the proximal end of the device from the distal end of
10 the introducer and withdrawing the introducer and the guide tube after deploying the device.

31. A method of deploying a mitral valve annulus reshaping device within the coronary sinus of a heart, the method
15 including the steps of:

inserting a guide wire into the coronary sinus of the heart;

advancing the elongated mitral valve annulus reshaping device on the guide wire and into the coronary sinus into a
20 position such that the device at least partially encircles the mitral valve of the heart.

32. The method of claim 31 wherein the advancing step further includes the steps of slidingly mounting an elongated
25 flexible introducer onto the guide wire proximal to the device, engaging the distal end of the introducer with the proximal end of the device, and pushing the device distally into the coronary sinus with the introducer.

30 33. The method of claim 32 including the further step of withdrawing the introducer after deploying the device.

34. The method of claim 33 wherein the engaging step includes releasably locking the proximal end of the device to the distal end of the introducer.

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35. The method of claim 34 including the further step of releasing the proximal end of the device from the distal end of the introducer prior to withdrawing the introducer.

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36. The method of claim 32 including the further steps of: providing an elongated flexible guide tube having an inner lumen, the inner lumen having a cross sectional dimension greater than the cross sectional dimension of the guide wire;

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feeding the guide tube into the coronary sinus of the heart over the guide wire with the guide wire within the inner lumen of the guide tube; and

wherein the pushing step includes pushing the device along the guide wire and within the guide tube.

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37. The method of claim 36 wherein the engaging step includes releasably locking the proximal end of the device to the distal end of the introducer.

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38. The method of claim 37 including the further steps of releasing the proximal end of the device from the distal end of the introducer and withdrawing the introducer and the guide tube after deploying the device.

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39. A mitral valve annulus device for reshaping and effecting the condition of a mitral valve annulus of a heart

comprising a resilient member having a cross sectional dimension for being received within the coronary sinus of a heart and having a longitudinal dimension having an arched configuration for partially encircling the mitral valve and exerting an inward pressure on the mitral valve when within the coronary sinus adjacent the mitral valve for reshaping at least a portion of the mitral valve annulus, the device having a distal end including a bent portion to avoid exerting pressure on the circumflex artery at the crossover point of the circumflex artery and the coronary sinus.

40. A mitral valve annulus therapy device comprising a generally C-shaped clip member formed of resilient material for exerting a substantially radially inward force on the mitral valve annulus when placed in the coronary sinus of a heart about and adjacent to the mitral valve, the device having a distal end including a bent portion to avoid exerting pressure on the circumflex artery at the crossover point of the circumflex artery and the coronary sinus.

41. An assembly for effecting the condition of a mitral valve annulus of a heart comprising:

guide wire means for extending along a predetermined path into the coronary sinus of the heart; and

mitral valve annulus reshaping means for sliding along the guide wire means and being advanced into the coronary sinus of the heart.

42. The assembly of claim 41 wherein the guide wire means comprises an elongated coil.

43. The assembly of claim 41 wherein the mitral valve annulus reshaping means has opposed ends and includes guide wire engaging means at at least one of the opposed ends.

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44. The assembly of claim 43 wherein the guide wire engaging means includes a bore dimensioned to permit the guide wire means to pass therethrough.

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45. The assembly of claim 44 wherein the reshaping means further includes channel means extending between the opposed ends for confining the guide wire means.

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46. The assembly of claim 44 wherein the bore of the guide wire engaging means is cylindrical in configuration.

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47. The assembly of claim 46 wherein the reshaping means includes guide wire channel means extending between the opposed ends and aligned with the bore for confining the guide wire means.

48. The assembly of claim 41 wherein the guide wire means is formed of a material visible under X ray fluoroscopy.

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49. The assembly of claim 41 wherein at least a portion of the reshaping means is visible under X ray fluoroscopy.

50. The assembly of claim 41 wherein the reshaping means is visible under X ray fluoroscopy.

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51. The assembly of claim 41 further including elongated introducer means configured to be slidably received on the

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guide wire means proximal to the reshaping means for pushing the
reshaping means along the guide wire means.

52. The assembly of claim 51 wherein the introducer means
5 comprises an elongated coil.

53. The assembly of claim 51 wherein the reshaping means
includes a proximal end, the introducer means includes a distal
end, and wherein the assembly further includes releasable
10 locking means for releasably locking the proximal end of the
reshaping means to the distal end of the introducer means.

54. The assembly of claim 53 wherein the releasable
locking means comprises a locking pin and a complimentary
15 detented locking groove.

55. The assembly of claim 51 further including guide tube
means having an inner lumen dimensioned for receiving the guide
wire means and the reshaping means and introducer means when the
20 reshaping means and introducer means are slidably received on
the guide wire means.

56. A mitral valve annulus constricting device for
reshaping and effecting the condition of a mitral valve annulus
25 of a heart comprising a resilient member having a cross
sectional dimension for being received within the coronary sinus
of a heart and having a longitudinal dimension having an arched
configuration for partially encircling the mitral valve and
exerting an inward pressure on the mitral valve when within the
30 coronary sinus adjacent the mitral valve for constricting the
mitral valve annulus, the device having a distal end, a proximal

end, a bore through at least one of the ends, and a channel extending between the ends, the channel and bore permitting the device to be slidingly received on a guide wire.

- 5 57. A mitral valve annulus therapy device comprising a generally C-shaped member formed of resilient material for exerting a substantially radially inward force on the mitral valve annulus when placed in the coronary sinus of a heart about and adjacent to the mitral valve, the device having a guide wire
10 receiving structure that slidingly mounts the device on a guide wire.